HIMA
HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

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Dockets Management Branch
Food and Drug Administration
Mail Code HFA-305
5630 Fishers Lane - Room 1061
Rockville, MD 20852

Re: Docket No. 98N-0583; Exports: Notification and Recordkeeping Requirements

Dear Madam or Sir:

These comments are submitted by the Health Industry Manufacturers Association (HIMA) in response to the Food and Drug Administration's (FDA's) proposed regulation [64 Fed. Reg. 15944 (April 2, 1999)] to establish notification and recordkeeping requirements under the FDA Export Reform and Enhancement Act of 1996 (1996 Export Law). HIMA is a Washington, D.C. based trade association and the largest medical technology association in the world. HIMA represents more that 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture more than 90 percent of the $58 billion of health care technology products purchased annually in the United States, and more than 50 percent of the 137 billion purchased annually around the world.

General Comments

The 1996 Export Law was designed to provide streamlined, less restrictive requirements for pharmaceutical and medical device exports. It simplified the requirements for exporting products to other countries for investigation and/or marketing, recognizing that each country is responsible for making its own determination whether products are suitable to enter its borders.

During the legislative process, Congressman Upton, a major force behind the 1996 Export Law, was concerned that future agency action would erode the purpose of the 1996 Export Law. To this end Congressman Upton stated, "[i]t is very clear that the majority of the Members believe that the export provisions are a trade issue first and foremost." (104 Cong. Rec. H4094, April 25, 1996, statement of Rep. Upton). He also stated, "[t]he FD&C Act, under this amendment, is altered to make it easier to export drugs and devices..." (Id.) Congressman Upton concluded his remarks by stating,

> "If it were up to me, there would be almost no restrictions on the export of medical products to nations which allow them for sale. In my mind, the job of the FDA is to protect the health and safety of the United States, and it is not to play health product

World Leaders in Health Care Innovation
1200 G STREET, N.W., SUITE 400
WASHINGTON, D.C. 20005-3814
(202) 783-8700 FAX (202) 783-8750
www.himanet.com

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> policeman to the rest of the world. If a product is manufactured in accordance with the requirements and specifications of a foreign government, then I believe that it is insane for this country to deny the opportunity to manufacture this product here. No other nation on the face of this earth restricts the manufacture of medical products for export, because they know the value of these manufacturing jobs. While I believe that this is a true compromise, and it is, I also believe that we can and should do more to liberalize the treatment of trade in health products. It's about time we begin again to export products—not jobs. " (104 Cong. Rec. H4095, April 25, 1996, statement of Rep. Upton).

The proposed rule imposes significant additional burdens on manufacturers that export pharmaceuticals and medical devices. These extensive notification and recordkeeping requirements imposed on U.S. medical product manufacturers by this proposed rule are in direct conflict with Congressional intent to eliminate impediments to U.S. exports of medical products. These proposed requirements contravene both the letter and spirit of the 1996 Export Law.

The proposed rule repeats the same objectionable requirements contained in the FDA guidance document on imports and exports [see 63 Fed. Reg. 32219 (June 12, 1998).] HIMA submitted detailed comments on this issue to FDA on November 24, 1998 [Docket No. 98D-0307] and incorporates those comments by reference here.

In view of the overly burdensome nature of the proposed requirements, which would have the result of taking the export process back to its cumbersome and anti-competitive pre-1996 days, HIMA urges the FDA to: (i) withdraw the proposed rule and guidance document, (ii) reconsider the comments to Docket No. 98D-0307 and review the comments submitted to Docket No. 98N-0583, and (iii) if necessary, propose simple notification and recordkeeping requirements consistent with the goals of current law.

Specific Comments

Proposed 21 C.F.R. §1.101(b) – recordkeeping requirements for devices exported under or subject to Section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA)

This section proposes that records be maintained for at least five years from the date of exportation. A five year record retention period is excessive. A two year record retention period is more appropriate and consistent with the medical device quality system regulation's record retention provision in 21 C.F.R. §820.180(b).

In the case of multiple shipments of the same type of product, the record retention period should run from the date of last exportation.

Proposed 21 C.F.R. §1.101(b)(1) – records demonstrating that the product meets the foreign purchaser's specifications

This section is too restrictive in its requirements for separate descriptions and lists of detailed product specifications requested by the foreign purchaser. There are many examples of appropriate documentation for such a demonstration; two are highlighted below.

1. The foreign purchaser's specifications are usually simply the product description as it has been approved in the country of sale. There is no reason to insist on an additional document, when the product has been approved for sale in a foreign country. The labeling claims for the product as exported should be sufficient. This regulation appears to imply that all exported product is exported to a specific buyer, and not simply shipped to a company warehouse in a foreign locale, from which it will be sold to many foreign buyers.

2. Many products, in vitro diagnostic devices for example, are not manufactured to unique purchaser specifications. Rather, such products are offered for sale to the general laboratory/scientific community. In these cases, it is the manufacturer's package insert which describes the product specifications. A manufacturer's package insert is appropriate documentation to demonstrate that product meets the specifications of a foreign purchaser.

Proposed 21 C.F.R. §1.101(b)(2) – records demonstrating that the product does not conflict with the laws of the importing country

This section states that the only way in which a manufacturer may satisfy this demonstration is to obtain a letter from a foreign government agency, department, or other authorized body. HIMA vehemently objects to this overly restrictive, prohibitive requirement.

Obtaining letters from foreign governments is an incredibly burdensome task. There is no evidence to suggest that foreign governments will be able to provide such letters. In addition, any contact lists are virtually impossible to keep current, leaving manufacturers with no idea of whom to contact in the foreign government at any particular time. The process to obtain such a letter could take up to six months, and possibly more, which would lead to a significant delay in the ability to export product to that country. This in turn would result in U.S. companies being disadvantaged in their ability to participate effectively in a worldwide marketplace.

The law merely requires a demonstration that the exported product does not conflict with the laws of the importing country. The statutory language does not restrict the methods by which such a demonstration is to be made. Indeed, this legal requirement had been in place prior to the 1996 Export Law, and device manufacturers have successfully used many mechanisms to

comply with this requirement to FDA's satisfaction. A number of available mechanisms are described below.

1. The European Union (EU) is a collection of countries with a single system for approving the sale of medical devices. Many of these products are certified by notified bodies (non-governmental organizations) and others are self-certified. These requirements are already approved by the EU as a valid means for allowing the marketing of such products in all the countries composing the EU. Requiring additional documentation is redundant. For countries who are members of the EU or who adhere to the various Device Directives (e.g. Medical, EMC, IVD), obtaining a CE mark for products to be exported to these Member States should automatically establish compliance with the requirement to demonstrate that the exported product does not conflict with the laws of the importing government.

2. For those countries in which few or no requirements for marketing exist, an import permit should be ample evidence of legal sale in the country.

3. A letter or memo from a company official in the foreign country, a distributor in the foreign country, the foreign subsidiary of the U.S. company, an attorney (either in the foreign country or the U.S.), or a government authority in the foreign country, can provide an acceptable review of the country's product regulatory system and a determination that the exported product does not conflict with the laws of the importing country.

Proposed 21 C.F. R. §1.101(b)(4) – records demonstrating that the product is not sold or offered for sale in the United States

It is usually quite difficult to prove a negative, and it is extraordinary that FDA would expect a manufacturer to provide documentation proving that a product intended for export is not sold in the U.S. The information suggested in the proposed regulation, such as documentation concerning the product labeling and information about similar products sold in the U.S., would not provide such proof, but would only impose an additional paperwork burden on the exporter.

In fact, to comply with Section 801(e)(1)(C) of the FFDCA, manufacturers label the outside shipping package 'for export only.' This alone should be a sufficient confirmation that the product is not offered for sale in the United States. To require additional documentation beyond this procedure is excessive.

In the event that the labeling of the outside shipping package is not considered sufficient documentation that the product is not offered for sale in the United States, manufacturers should have the flexibility to use any legitimate business method to document that the product is not marketed in the United States. Examples of potential methods include, but are not limited to, the suggestions below.

1. One readily available record that could provide the appropriate documentation is a company's device listing record (FDA Form 2892). On this form, a company lists the products it markets in the United States. If the product to be exported does not appear as a listed product, it can be concluded that the product is not offered for sale in the United States.

2. Another record that can be used to document products marketed in the United States would be a price list or a product catalogue. Companies generally use a price list (either paper or electronic) as the starting point for customer orders. If a product is not in the U.S. price list, it can be concluded that the product is not offered for sale in the United States.

3. A company should also have the option to provide a certification (declaration) that the product is not sold in the United States. The declaration would be maintained in the company's files and available to FDA during the routine inspection process.

Proposed 21 C.F.R. §1.101(c) – additional recordkeeping requirements for partially processed biologics exported under Section 351(h) of the Public Health Service Act

For partially processed biologics, the1996 Export Law amended Section 351(h) of the Public Health Service Act to eliminate export restrictions, if the product is (i) manufactured, processed, packaged, and held in conformity with current GMP requirements, or (ii) meets international manufacturing standards as certified by an international standards organization recognized by FDA, and (iii) meets the requirements of Section 801(e)(1) of the FFDCA. The proposed rule attempts to impose a requirement that is not authorized by the statute and extends well beyond what is necessary to document compliance with Sections 351(h) and 801(e)(1). Specifically, the proposed requirement for manufacturers to keep copies of all labeling that accompanies the exported partially processed biological product is burdensome, unnecessary, exceeds the authority and intent of the law, and should be eliminated.

Proposed 21 C.F.R. §1.101(d)(1) – notification requirements for devices exported under Section 802 of the FFDCA

This section proposes requirements that are overly burdensome and beyond the scope of the current law. The current law states that for exports to listed countries, a manufacturer must provide to FDA a "simple notification" identifying the drug or device at the time when the exporter first begins to export the drug or device. [FFDCA, Section 802(g)]. For exports to non-listed countries, the "simple notification" is to consist solely of the identification of the drug or device and the country to which the drug or device is being exported. [Id.] FDA's proposal expands the scope of the "simple notification" by stating that all notifications to FDA, whether for exports to listed or non-listed countries, must identify the country to which the product

is being exported. Congress specifically did not establish such a notification scheme. FDA attempts to justify this expansion of the statute by asserting it is necessary for consulting with other countries in the event the agency determines the product is an imminent hazard or is ultimately disapproved.

Section 802(g) of the FFDCA requires all exporters to maintain records of the devices exported and the countries to which they were exported. In the exceedingly rare instances of a product being declared an imminent hazard or disapproved for marketing, FDA can request the records from the relevant company concerning the countries to which the product was exported. This would be a more narrowly tailored, rational mechanism to achieve the stated goal. As written, the proposal is casting a wide net to catch a few guppies at tremendous cost to the other fish. FDA should not require notifications beyond the literal terms of the statute.

For additional simplicity, a "simple" notification should be allowed to list multiple countries, in the event that at the time of export the product is sent to more than one country.

To speed the notification process, FDA should institute a place on its Internet web site with a 'fill in the blank' format on which companies can directly input the information. This would be quick and easy for both the manufacturer and the FDA, as the agency can avoid expending additional time to input information from a hard copy paper submission by a manufacturer into an electronic FDA database.

In addition, this section of the rule would require a notification to FDA for exports that are authorized under Section 802(d) of the FFDCA [i.e. "a drug or device intended for formulation, filling, packaging, labeling, or further processing in anticipation of market authorization in any country ... for use in accordance with the laws of that country."] The literal terms of the statute do not require any such notification. To require this notification is inefficient for both FDA and manufacturers. Exports under Section 802(d) are to be exempt from any type of FDA notification procedure, as are exports under Section 802(c) (for investigational use).

Proposed 21 C.F.R. §1.101(e) – recordkeeping requirements for products subject to Section 802(g) of the FFDCA

This section proposes that records be maintained for at least five years from the date of exportation. A five year record retention period is excessive. A two year record retention period is more appropriate and consistent with the medical device quality system regulation's record retention provision in 21 C.F.R. §820.180(b).

This section also contains a separate requirement that the records kept include the consignee's name and address. If such a separate requirement is retained apart from the existing requirements in the quality system regulation, it should be made clear that the name and address

of a distribution center is an appropriate substitute for the name and address of a particular consignee, since products are often exported to a distribution center outside of the United States.

Analysis of Impacts – 64 Fed. Reg. at 15947

FDA seriously underestimates the number of export records per firm. An example demonstrating this appears below.

A company in HIMA's membership currently markets its products in approximately 90 countries. The company markets to both the consumer and professional users, and often provides product packaging and labeling configurations which are best suited to meet an individual country's market. This would represent approximately 600 different packaging and labeling configurations.

To meet the proposed recordkeeping requirements, new records would be required for at least 500 of these configurations. The estimated cost for updating these records is as follows:

Cost to update existing records:	$30/hr x 4 hours x 500 = $60,000
Recordkeeping costs:	$100 x 500 = $50,000

For new product introductions, the estimated cost for preparation and recordkeeping is as follows:

Cost to prepare records:	$30/hr x 4 hours x 84 = $10,080
Recordkeeping cost:	$100 x 84 = $8,400

In summary, the initial estimated costs for recordkeeping would be $110,000 with an estimated annual cost for new product introductions between $18,480 to $55,440 (based on one to three worldwide product introductions per year.)

FDA should be mindful of the significant costs to industry of implementing excessive notification and recordkeeping requirements. These costs must be considered in determining whether a regulation is necessary, as well as the scope of any regulation, to implement the clear statutory language of the 1996 Export Law.

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HIMA appreciates the opportunity to submit these comments.

Sincerely,

Carolyn D. Jones
Associate Vice President, Technology and Regulatory Affairs

Marlene K. Tandy, M.D., J.D.
Director, Technology and Regulatory Affairs
and Associate General Counsel